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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,049 | 06/22/2001 | Yasuki Kato | 506.40278X00 | 1134 |

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| EXAMINER | |
|---|---|
| SRIVASTAVA, KAILASH C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/869,049 | KATO ET AL. | |
| | Examiner | Art Unit | |
| | Dr. Kailash C. Srivastava | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,9,13,17,21,23 and 61-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,13,17,21,23,62,66,68 and 70* is/are rejected.

7)☒ Claim(s) *5, 9 and 61-80* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action mailed 1 April 2004 has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 December 2004 together with amendment filed 1 October 2004 has been entered. ACCORDINGLY, an RCE has been established and the action on RCE follows.

2. Applicants' response and Amendment filed 1 October 2004 in response to Office Action mailed 1 April 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

## *CLAIMS STATUS*

3. Claims 61-80 have been added.

4. Claims 6-8, 10-12, 14-16, 18-20, 22 and 24-60 have been cancelled.

5. Claims 1-5, 9, 13, 17, 21 and 23 have been amended.

6. Claims 1-5, 9, 13, 17, 21, 23 and 61-80 are pending and are examined on merits.

## *Objection To Claims – Minor Informalities*

7. Claims 5, 9, 13, 17, 23 and 61-80 objected to because of the following informalities:

- The phrase, "which is" in Claims 5, 9, 13, 17 and 23 is redundant and does not in any way extend the claimed subject matter. Examiner suggests to delete said phrase in said Claims.
- As pointed out above, Claim 5 covers the subject matter claimed in Claim 9. Therefore, Claim 64 is redundant and should be canceled. Furthermore, dependency for Claims 62, 66, 68 and 70 should be appropriately corrected to depend from Claims 5, 13, 17 and 23 respectively.
- Claims 61 and 71 are repetition of recitation at Claim 5, Lines 1-2 and 7-10, and Lines 1-6 and 10-16 respectively,
- Claims 63 and 73 are repetition of recitation at Claim 9, Lines 1-2 and 7-9, and Claim 9, Lines 1-6 and 9-13 respectively,

- Claim 65 and 75 are repetition of recitation at Claim 13, Lines1-2 and 7-10, and Claim 13, Lines 1-6 and 10-16 respectively,

- Claims 67 and 77 are repetition of recitation at Claim 17, Lines1-2 and 7-8 and, Claim 17, Lines 1-6 and 9-13 respectively,

- Claims 69 and 79 are repetition of recitation at Claim 23, Lines 1-2 and 7-9, and Claim 23, Lines 1-6 respectively,

- Claims 72, 76, 78 and 80 are dependent on Claims 71, 73, 77 and 79. As discussed *supra,* limitations for Clams 71, 73, 77 and 79 are already recited in Claims 5, 9, 17 and 23. Furthermore, limitations for Claims 72, 74, 76, 78 and 80 are recited in Claims 62, 64, 66 and 70 that are dependent on Claims 5, 9, 13, 17 and 23.

## ***Claim Rejections - 35 U.S.C. § 112***

### *First Paragraph Rejections*

8. Claims 1-5, 13, 17, 21, 23 and newly presented Claims 61-80 dependent on Claims 1-5, 13, 17, 21 and 23 stand rejected under 35 U.S.C. 112, first paragraph for the reasons of record in previous Office Actions mailed July 1 2003 and April 1, 2004.

9. In response to the enablement/scope rejections for Claims 1-5, 13, 17, 21 and 23 under 35 U.S.C. § 112, first paragraph in the Office Actions cited *supra*, applicants argue that applicants have amended the Claims to clearly recite the compounds II and III components and components in Groups B and C have now been limited to doxorubicin and a peptide, whereas Group A is limited to lactose and sialyllactose.

Applicant s' arguments filed 01 October 2004 in regard to rejections made in the Office Action mailed 01 April 2004 have been fully and carefully considered but they are not persuasive. The rejections under 35 U.S.C. § 112, first paragraph are adhered to for the reasons of record and the additional reasons discussed *infra.*

10. In view of applicants' amendment filed 01 October 2004 together with RCE filed 01 December 2004, following is a new rejection to Claims 1-5, 13, 17, 21, 23 and newly presented Claims 61-80 dependent on Claims 1-5, 13, 17, 21 and 23 under 35 U.S.C. §112, first paragraph.

11. Claims 1-5, 13, 17, 21, 23 and newly presented Claims 61-80 rejected under 35 U.S.C.§112, first paragraph, because said claims do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with those claims. Claims are directed to a "pharmaceutical compound" made by reacting compounds II and III. Said compound II is selected from Group B comprised of doxorubicin and a peptide, said peptide is one among insulin or enkephalin; whereas said compound III is selected from Group A, and Group A is comprised of lactose or sialyllactose. The amino group of said compound II reacts with aldehyde group of the sugar (i.e., lactose or sialyllactose) to make said pharmaceutical compound and upon changes in pH, said pharmaceutical compound having amino group (i.e., peptide or insulin or enkephalin) releases said amino group (i.e., insulin or enkephalin).

From the record of the presently filed written disclosure, the specification does not reasonably provide evidence of the claimed invention because the written disclosure exemplifying composition cited *supra* shows a compound formed as a result of reaction between lactose or sialyllactose and insulin. The resulting compound, with changes in pH releases the moiety having a free amino group (i.e., insulin). The written description as presented, is without any showing of a compound comprising doxorubicin together with insulin, doxorubicin together with enkephalin, or a pharmaceutical compound comprising doxorubicin together with enkephalin or doxorubicin together with insulin reacted with lactose or sialyllactose, wherein upon changes in pH the enkephalin+doxorubicin or insulin +doxorubicin moiety of said compound is released from said compound (See Pages 7-17 of the specification). Based on the description provided in the specification, a person of skill would not be able to practice the invention as claimed. A person of skill would not be able to practice the invention because undue experimentation will be required to practice the invention cited *supra.* Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to delineate a pharmaceutical compound made by reacting aldehyde group of lactose or sialyllactose with the amino group of a compound comprising doxorubicin together with insulin or enkephalin; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). This is because from the record of the present disclosure there is no showing of a compound comprising doxorubicin together with a free amino group comprising moiety, wherein said free amino group comprising moiety is a peptide and said peptide is one of insulin or enkephalin, Since there is n showing for said compound (i.e., Claimed Group B compound), the rest of the Wand test factors are automatically qualified.

## *Second Paragraph Rejections*

12. In view of applicants' amendment filed 1 October 2004, following are new rejections to Claims 1-5, 13, 17, 21, 23 and newly presented Claims 62, 64, 66, 68 and 70 under 35 U.S.C. §112, second paragraph.

13. Claims 1-5, 13, 17, 21, 23 and newly presented Claims 61-80 rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1-5, 13, 17and 23 as written are very confusing, unclear and difficult to understand. Applicants have attempted to clarify these claims, however, these claims remain unclear and difficult to understand. Applicants are requested to clearly, concisely and succinctly rewrite the claims in such a manner that the claims clearly indicate the applicants' invention. Examiner suggests to cancel all the current claims and re-write them along the lines of Claims 61 and 71 for e.g., that is The subject matter of Claim 5 may be claimed in three different Claims along the lines that Claims 61 and 71 were written. Thus, Claims 1-4 remain as they are, but Claim 5 will be split in three different Claims (e.g., Claims 81-83) and similarly the subject matter for Claims 13, 17 and 23 may also be claimed along same lines. Applicants are reminded to ensure that no new matter is added while they clearly and succinctly re-write the claims.

- In Claim 5 at Line 5, the phrase "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 5 depends from Claim 1, and Claim 1 does not recite "pharmaceutical carrier" as a limitation.

- In Claim 13 at Lines 5, 9 and 15, the phrase "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 13 depends from Claim 3, and Claim 3 depends from Claim 1. None of Claim 1, or 3 recite the limitation "pharmaceutical carrier".

- In Claim 17 at Line 4, the limitation "insulin is modified with a "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 17 depends from Claim 4, and Claim 4 depends from Claim 1. None of Claim 1, or 4 recite the limitation "insulin is modified with a "pharmaceutical carrier".

- In Claim 17 at Lines 4-5, 7 and 13, the phrase "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 17 depends from Claim 4, and Claim 4 depends from Claim 1. None of Claim 1, or 4 recite the limitation "pharmaceutical carrier".

- In Claim 23 at Line 4, the limitation "enkephalin is modified with a "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 23 depends from Claim 21, and Claim 21 depends from Claim 1. None of Claim 1, or 21 recite the limitation "insulin is modified with a "pharmaceutical carrier".

- In Claim 23 at Lines 5, 7, 9 and 14, the phrase "pharmaceutical carrier" lacks sufficient antecedent basis because Claim 23 depends from Claim 21, and Claim 21 depends from Claim 1. None of Claim 1, or 21 recite the limitation "pharmaceutical carrier".

All other claims depend directly or indirectly from the rejected claims (e.g., Claim 26) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

## ***CONCLUSION***

14. For aforementioned reasons, no Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)-272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571)-272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (571)-272-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571)-272-0923

February 22, 2005

LEON B. LANKFORD, JR.
PRIMARY EXAMINER